

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: October 18, 2012

Subject: Fludioxonil. Revised Occupational and Residential Exposure Assessment for Proposed Uses on Post-Harvest Pome Fruit.

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The Registration Division (RD) requested that the Health Effects Division (HED) conduct an exposure and risk assessment for the new proposed uses of fludioxonil on post-harvest pome fruit. The formulated end-use product evaluated in this assessment is eFOG-80 FDL (EPA Reg. # 64864-AT; containing 8% fludioxonil). This product is a special liquid form of fludioxonil intended for use with a thermal electrofogger to form a fine fog. This memorandum serves as HED's assessment of occupational and residential exposure and risk from the proposed use of fludioxonil.

It is HED policy to use the best available data to assess exposure. Sources of generic data, used as surrogate data in the absence of chemical-specific data, include the Pesticide Handlers

Exposure Database Version 1.1 (PHED 1.1), the Agricultural Handler Exposure Task Force (AHETF) database, the Residential SOPs (Turf), and the Agricultural Reentry Task Force (ARTF). Some of these data are proprietary (e.g., AHETF data), and subject to the data protection provisions of FIFRA.

This memorandum was reviewed by the Exposure Science Advisory Committee (ExpoSAC) on August 30, 2012.

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1.0 Executive Summary

This document presents an occupational and residential exposure/risk assessment for the proposed application of fludioxonil to post-harvest pome fruit treatment by thermal electrofogging. The proposed uses are anticipated to result in occupational exposure, but not residential exposure. There are currently registered residential uses that have been summarized in this document.

Proposed Use Profile:

In the current action, the registrant, Pace International, LLC, proposes a new pesticide registration of eFOG-80 FDL, an end-use product containing 8% fludioxonil for post-harvest use on pome fruit to reduce damage from blue and gray mold, Bull's eye rot, Rhizopus rot, Bitter rot, Sphaeropsis rot, Phacidiopycnis rot, and White rot. The proposed label states that eFOG-80-FDL is a "special liquid form of fludioxonil intended for use with a thermal electrofogger to form a fine fog." The proposed application rate is 0.68 pounds of fludioxonil per gallon or 60 milliliters per metric ton (2200 lb) of fruit or approximately 2 fluid ounces per US ton. The label states to apply to fruit as close to harvest as possible and no more than 15 days after harvesting and prior to placing in storage.

Exposure Profile

There is a potential for short- and intermediate-term occupational exposure to fludioxonil during mixing, loading, and other handling tasks; for short- and intermediate-term occupational exposure during post-application activities. Note there is no short- or intermediate term dermal endpoint. Chronic exposure is not expected for the proposed use patterns associated with fludioxonil.

The proposed label eFOG-80 FDL directs handlers (including mixers, loaders, persons cleaning or setting up the fogging equipment and persons handling treated fruit still wet with product) to wear long sleeved shirt and long pants, chemical resistant gloves, shoes and socks, and protective eyewear (such as goggles, safety glasses or a face shield). The label states that while respiratory protection is not normally required when using this product, fogging applicators must keep a respirator with an organic-vapor removing cartridge readily available in case of rare instance where fog may be blown back to the applicator, such as an equipment malfunction or insufficient room seal.

Hazard Concerns:

Fludioxonil is of low acute toxicity, since technical fludioxonil is in Toxicity Category III or IV for the full battery of acute tests and is not a dermal sensitizer. No short- or intermediate-term dermal point of departure (POD) was selected for fludioxonil. The short-term inhalation POD is a No Observable Adverse Effect Level (NOAEL) of 10 mg/kg/day based on decreased weight gain during the dosing period in a rabbit developmental study. The intermediate-term inhalation POD is a NOAEL of 3.3 mg/kg/day based on decreased weight gain in female dogs during weeks one to thirteen in a one-year dog feeding study. Since no inhalation absorption data are available, toxicity by the inhalation route is considered to be equivalent to the estimated toxicity by the oral route of exposure. A body weight of 80 kilograms is used in both short- and

intermediate-term inhalation assessments to represent the bodyweight of an average adult. Fludioxonil is classified as “not likely to be carcinogenic to humans;” therefore, a cancer assessment was not conducted.

HED’s level of concern (LOC) for non-cancer risks (i.e., level of concern for MOEs or Margins of Exposure) is defined by the uncertainty factors. HED applies a 10X factor to account for inter-species extrapolation and a 10X factor to account for intra-species variation. The total uncertainty factor that is applied to occupational and residential risk assessments is 100X for short- and intermediate-term inhalation risks.

Residential Exposure/Risk:

There are no new residential uses proposed for fludioxonil; however, fludioxonil is registered for use in residential areas, including parks, golf courses, athletic fields, residential lawns, and ornamentals. In a previous risk assessment (Memo, L. Venkateshwara, 1/31/12, D389982), HED reassessed the existing residential turf uses of fludioxonil using the 2012 Residential SOPs. Short-term inhalation risk estimates to residential handlers did not exceed HED’s LOC for all scenarios (i.e., MOEs \geq 100). Post-application incidental oral risk estimates also did not exceed HED’s LOC for any of the scenarios assessed (i.e., MOEs \geq 100).

Based on the Agency's current practices, a quantitative residential post-application inhalation exposure assessment was also not performed for fludioxonil at this time primarily because of the low acute inhalation toxicity (Toxicity Category IV) and low vapor pressure of fludioxonil (2.9×10^{-9} mm Hg at 25 °C). If new policies or procedures are developed, the Agency may revisit the need for a quantitative post-application inhalation exposure assessment for fludioxonil.

Occupational Handler Exposure:

Occupational handlers are anticipated to have short- and intermediate-term dermal and inhalation exposures. However, since no short- or intermediate-term dermal points of departure were selected, only inhalation exposures to fludioxonil are assessed. HED has determined that risks are not of concern for short- and intermediate term exposures (i.e., MOEs >100) with the PPE required on the label.

Occupational Postapplication Exposure:

Since no short- or intermediate-term dermal PODs were selected, postapplication dermal exposures and risks were not quantitatively assessed for the proposed post-harvest uses on pome fruit. Post-application inhalation exposure is expected to be negligible since the proposed eFOG-80 FDL label requires that no entry into the treated room be allowed for 8 hours if there is no ventilation followed by one hour of mechanical ventilation, or for 24 hours with no ventilation.

Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, the Agricultural Handler Exposure Task Force (AHETF) database, are subject to ethics review pursuant to 40 CFR 26, have received that review, and are compliant with applicable ethics requirements. For certain studies that review may have included review by the Human Studies Review Board.

Descriptions of data sources as well as guidance on their use can be found at <http://www.epa.gov/pesticides/science/handler-exposure-data.html> and <http://www.epa.gov/pesticides/science/post-app-exposure-data.html>.

2.0 Summary of Conclusions/Data Deficiencies

There are no occupational/residential risk estimates of concern associated with the proposed new uses of fludioxonil. There are no data gaps in the exposure database.

3.0 Hazard Characterization

The toxicology database for fludioxonil is considered complete for risk assessment purposes. The acute toxicity and toxicological points of departure for occupational/residential exposure and risk assessment for fludioxonil are summarized in Tables 1 and 2, respectively. Fludioxonil has low acute toxicity – Toxicity Category IV for acute inhalation and acute oral toxicity and Category III for acute dermal toxicity. It is classified as Category III for primary eye irritation and Category IV for primary skin irritation. It is not a dermal sensitizer.

Guideline No.	Study Type	MRID No.	Results	Toxicity Category
870.1100	Acute Oral	43124105	LD ₅₀ > 5000 mg/kg	IV
870.1200	Acute Dermal	43124106	LD ₅₀ > 2000 mg/kg	III
870.1300	Acute Inhalation	43080019	LC ₅₀ = 2.636 m/L	IV
870.2400	Primary Eye Irritation	43124107	slight irritant	III
870.2500	Primary Skin Irritation	43124108	non-irritating	IV
870.2600	Dermal Sensitization	43080024	not a sensitizer	-

Exposure/Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental Oral Short-Term (1-30 days)	NOAEL = 10 mg/kg/day	UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	Rabbit developmental study LOAEL = 100 mg/kg/day based on Decreased weight gain during dosing period.
Incidental Oral Intermediate-Term (1-6 months)	NOAEL = 3.3 mg/kg/day	UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE = 100	Chronic toxicity in dogs LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs during weeks 1-52 of one-year dog feeding study

Table 2. Summary of Toxicological Doses and Endpoints for Fludioxonil for Use in Occupational Human-Health Risk Assessments.

Exposure/Scenario	Point of Departure	Uncertainty Factors	Level of Concern for Risk Assessment	Study and Toxicological Effects
Dermal Short-Term (1-30 days) and Intermediate-Term (1-6 months)	No hazard identified and therefore quantification is not required. There are no developmental concerns via the dermal route and no systemic toxicity was seen following dermal exposure.			
Inhalation Short-Term (1-30 days)	NOAEL= 10 mg/kg/day	UF _A =10x UF _H =10x	Occupational LOC for MOE = 100	Rabbit developmental study LOAEL = 100 mg/kg/day based on Decreased weight gain during dosing period.
Inhalation Intermediate-term (1-6 months)	NOAEL= 3.3 mg/kg/day	UF _A =10x UF _H =10x	Occupational LOC for MOE = 100	Chronic toxicity in dogs LOAEL = 35.5 mg/kg/day based on decreased weight gain in female dogs during weeks 1-52 of one-year dog feeding study
Cancer (oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.			

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no-observed adverse-effect level. LOAEL = lowest-observed adverse-effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of key data (i.e., lack of a critical study). MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

4.0 Use Profile

Table 3 provides a summary of the proposed uses of fludioxonil.

Table 3. Summary of Proposed Uses for Fludioxonil.

Crops	Treatment Type/Target of Application	Application Equipment	Maximum Application Rate ¹	Treatment Interval and Comments	Comments
eFOG-80-FDL (EPA Reg.# 64864-AT-EFOG-80-FDL)					
Pome Fruit	Post-harvest fruit prior to placing in storage	Apply only with electrofog machine	60 milliliters per metric ton (2200 lb) of fruit or 2 ounces per US ton (2000 lb) or 0.0106 lb ai per ton of fruit or 0.0000053 lb ai per lb of fruit	Apply to fruit as close to harvest as possible and no more than 15 days after harvesting, prior to placing in storage	Do not apply to fruit previously treated with fludioxonil via drench or dip/wash

¹ Rate = Maximum application rates specified on proposed labels.

5.0 Residential Exposure and Risk Estimates

There are no proposed residential uses at this time; however, fludioxonil is currently registered for use in residential areas, including parks, golf courses, athletic fields, residential lawns and ornamentals. In a previous assessment (Memo, L. Venkateshwara, 1/31/12, D389982), HED reassessed the existing residential turf uses of fludioxonil using the 2012 Residential SOPs. Short-term inhalation risk estimates to residential handlers did not exceed HED's LOC for all scenarios (i.e., MOEs \geq 100). Post-application incidental oral risk estimates also did not exceed HED's LOC for any of the scenarios assessed (i.e., MOEs \geq 100). The currently registered label for turf is Medallion® Fungicide EPA Reg. # 100-769. Medallion® Fungicide is a 50% WP in water-soluble packaging. The maximum single application rate for turf is 0.50 oz per 1000 ft² or 0.68 lbs ai/A. The maximum single application rate for ornamentals is 30 oz per 1000 ft² or 0.00094 lbs ai ft².

Table 4. Residential Handler Exposure and Risk Estimates for Fludioxonil.

Exposure Scenario	Application Rate ^a	Area Treated Daily (acres) ^b	Baseline Unit Exposures ^b (mg/lb ai)	Baseline Dose ^d (mg/kg/day)	Baseline MOE ^e
			Inhalation	Inhalation	Inhalation
Mixer/Loader/Applicator					
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Manually-pressurized Handwand to Turf	0.68 lb ai/A	0.023 acres	0.018	3.5E-06	2,800,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Backpack Sprayer to Turf	0.68 lb ai/A	0.023 acres	0.018	3.5E-06	2,800,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Hose- end sprayer to Turf	0.68 lb ai/A	0.5 acres	0.034	1.5E-04	69,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Sprinkler Can to Turf	0.68 lb ai/A	0.023 acres	0.034	6.7E-06	1,500,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Manually-pressurized Handwand to Gardens and Trees	0.00094 lb ai/ft ²	1200 ft ²	0.018	0.00025	39,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Backpack Sprayer to Gardens and Trees	0.00094 lb ai/ft ²	1200 ft ²	0.018	0.00025	39,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Hose- end sprayer to Gardens and Trees	0.00094 lb ai/ft ²	1200 ft ²	0.034	0.00048	21,000
Mixing/Loading/Applying Wettable Powder in Water-soluble Packaging with Sprinkler Can to Gardens and Trees	0.00094 lb ai/ft ²	1200 ft ²	0.034	0.00048	21,000

a. Application rates based on label for fludioxonil (Medallion® Fungicide, EPA Reg# 100-769).

b. Based on HED's Standard Operating Procedures for Residential Pesticide Exposure Assessment; Lawns/Turf (February 2012).

c. Baseline Inhalation; no respirator.

d. Dose (mg/kg/day) = daily unit exposure (mg/lb ai) x application rate (lb ai/A) x acres treated * absorption factor (inhalation = 100%) / body weight (80 kg).

e. MOE = NOAEL (10 mg/kg/day) / daily dose (mg/kg/day). Level of concern = 100.

Table 5. Short and Intermediate-Term Residential Post-application Exposure and Risk Estimates for Fludioxonil.

Lifestage	Post-application Exposure Scenario		Dose (mg/kg/day)	Short-term MOEs ⁴	Intermediate-term MOEs
Child 1 < 2 year old	Turf - sprays	Hand to Mouth ¹	0.0101	990	330
		Object to Mouth ²	0.00031	32,000	11,000
		Incidental Soil Ingestion	2.2E-05	450,000	150,000

1. Hand-to-Mouth = [Hand residue loading (mg/cm²)*(fraction hand surface area mouthed/event (0.127/event)*typical surface area of one hand (150 cm²))*(exposure time (1.5 hrs/day)*number of replenishment intervals/hr (4 intervals/hr))*(1-(1-saliva extraction factor (0.5))^(number of hand-to-mouth contact events per hour (13.9 events/hr); *Hand Residue Loading* = (fraction of ai on hands compared to total surface residue from dermal TC study (0.06)*dermal exposure (mg))/typical surface area of one hand (150 cm²).
2. Object-to-Mouth = ((Object Residue (μg/cm²)*CF1 (1.0E-3 mg/μg)*Object Surface Area Mouthed/Event (10 cm²/event))*(Exposure Time (1.5 hrs/day)*#Replenishment Intervals/hr (4))*(1-((1-Extraction by Saliva (0.48))^(#Object-to-Mouth Events/hr (8.8 events/hr)/#Replenishment intervals/hr))))/Body Weight (11kg).
3. Soil Ingestion = (Soil Residue (7.0746975 μg/g) *Ingestion Rate (50 mg/kg/day) *CF(0.000001))/Body Weight (11 kg).
4. MOE = NOEL/Daily Dose (mg ai/kg/day); Inhalation NOEL= 10 mg/kg/day, Oral NOEL = 10 mg/kg/day.

Inhalation

Based on the Agency's current practices, a quantitative post-application inhalation exposure assessment was not performed for fludioxonil at this time. However, volatilization of pesticides may be a potential source of post-application inhalation exposure to individuals nearby to pesticide applications. The Agency sought expert advice and input on issues related to volatilization of pesticides from its Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) in December 2009. The Agency received the SAP's final report on March 2, 2010 (<http://www.epa.gov/scipoly/SAP/meetings/2009/120109meeting.html>). The Agency is in the process of evaluating the SAP report and may, as appropriate, developing policies and procedures, to identifying the need for and, subsequently, the way to incorporate post-application inhalation exposure into the Agency's risk assessments. If new policies or procedures are put into place, the Agency may revisit the need for a quantitative post-application inhalation exposure assessment for fludioxonil.

5.1 Residential Risk Estimates for Use in Aggregate Assessments

Table 6 reflects the residential risk estimates that are recommended for use in the aggregate assessment for fludioxonil.

- The recommended residential exposure for use in the adult aggregate assessment reflects inhalation exposure from mixing/loading/applying a wettable powder in water-soluble packaging with hose end sprayer (both for turf and gardens).
- The recommended residential exposure for use in the children 1<2 years old aggregate assessment reflects incidental oral exposures from post-application exposure to outdoor treated turf.

Table 6. Recommendations for the Residential Exposures for the Fludioxonil Combined Residential Risk Calculations. ¹									
Lifestage	Handler Exposure		Residential Handler Total Exposure (mg/kg/day) ³	Residential Handler Total MOE ⁴	Post-application Exposure (mg/kg/day) ⁵			Residential Total Exposure (mg/kg/day)	Residential Total MOE ⁶
	(mg/kg/day) ²				Dermal	Inhalation	Oral		
Short-Term									
Adult Male	Handler: Treating Turf	0.000015	0.000495	20,200	N/A ⁷	N/A ⁷	N/A ⁷	N/A ⁷	N/A ⁷
	Handler: Treating Gardens/Trees	0.00048			N/A ⁷	N/A ⁷	N/A ⁷		
Child 1 < 2 years old	N/A ⁷	N/A ⁷	N/A ⁷	N/A ⁷	N/A ⁷	N/A ⁷	Hand-to-Mouth: 0.0101	0.0101	990
Intermediate-Term									
Child 1 < 2 years old	N/A ⁷	N/A ⁷	N/A ⁷	N/A ⁷	N/A ⁷	N/A ⁷	Hand-to-Mouth: 0.0101	0.0101	330

¹ Bolded risk estimates should contribute to the residential exposure portion of the aggregate assessment.

² Handler exposure represents high-end handler exposure (i.e., the highest handler exposure of all scenarios assessed).

³ For adults, residential total exposure combines the highest inhalation exposures (Table 4), where applicable. For young children, total residential exposure combines high-end post application incidental oral, where applicable (Table 5)

⁴ Total MOE = 1 / (1/Inhalation MOE Turf) + (1/Inhalation MOE Gardens). Inhalation NOAEL = 10 mg/kg/day

⁵ Post-application exposure represents high-end inhalation and/or incidental oral exposure for the relevant exposure duration

⁶ Total MOE = (1/Inhalation MOE) + (1/Incidental oral MOE). Inhalation NOAEL = 10 mg/kg/day; Incidental oral NOAEL = 10 mg/kg/day.

⁷ N/A = Not applicable.

6.0 Occupational Exposure and Risk Estimates

Based on the proposed use, exposure is possible for individuals that handle the end-use product, and for individuals that may enter the treatment area (in this case, a packinghouse room). The proposed use is a very specific use pattern (thermal electrofogger). Data for this specific exposure scenario are not available to HED. Therefore, surrogate data was used (see below). HED conducted a conservative assessment of short- and intermediate- term risks to handlers. Post-application dermal exposure was not quantitatively assessed since there is no dermal POD, and post-application inhalation exposure is expected to be negligible due to personal protective equipment (PPE) required on eFOG-80 FDL label, as well as the proposed label requires that no entry into the treated room be allowed for 8 hours if there is no ventilation followed by one hour of mechanical ventilation, or for 24 hours with no ventilation.

6.1 Occupational Handler Exposure/ Risk Estimates

An electrofogger is an automatic fogging machine which is located outside the area where the harvested pome fruit is stored and treated. The fog, which contains fludioxonil, is piped into the storage room, which is typically sealed tightly for climate control. The material is transferred from the product container into the fogging machine by pipe. The machine then slowly draws the solution out of the tank, heats it up to convert it to fog, and sends the fog into the storage room through a pipe. The fog is not released in the presence of the handler. Therefore, the only significant source of exposure is during the pouring of the end-use product into the fogging machine tank. This exposure was assessed as a mixer/loader scenario using AHETF (open mixing loading of liquids).

A separate applicator assessment was not conducted. Since the application of fludioxonil is mechanically automated for the thermal fogging machine. A mixer/loader assessment was performed and is considered to result in a conservative estimate of worker risk. There are no risk estimates that are of concern.

Application Rate: The application rate is the maximum rate identified on the proposed eFOG-80 FDL label. The maximum application rate for treatment of pome fruit using a thermal fogger is 0.0106 lb ai/ton (2000 lb) fruit, or 0.0000053 lb ai/lb fruit.

Unit Exposures (UE): It is the policy of HED to use the best available data to assess handler exposure. Sources of generic handler data, used as surrogate data in the absence of chemical-specific data, include the PHED 1.1, the AHETF database, the ORETF database, or other registrant-submitted occupational exposure studies. Some of these data are proprietary and subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting handler exposure that are used in this assessment, known as “unit exposures”, are outlined in the “Occupational Pesticide Handler Unit Exposure Surrogate Reference Table” (<http://www.epa.gov/opp00001/science/handler-exposure-table.pdf>), which, along with additional information on HED policy on use of surrogate data, including descriptions of the various sources, can be found at <http://www.epa.gov/pesticides/science/handler-exposure-data.html>.

The AHETF UE for mixer/loaders, open pour, liquids is 0.219 µg/lb ai for inhalation exposure (without a respirator).

Amount Treated: Information on amount of fruit treated per day was taken from e-mail correspondence from Bill Chism, BEAD, USEPA on August 5, 2012. For this assessment, it was assumed that 61,600,000 lbs of pome fruit is treated per day. This amount is based on the following assumptions:

- In the US, apples are the most common of pome fruit.
- In the 2007 Census of Agriculture, Washington State was the greatest producer of apples (http://www.agcensus.usda.gov/Publications/2007/Full_Report/Volume_1,_Chapter_2_US_State_Level/st99_2_032_032.pdf).
- An example of a typical packing house for this assessment is the Washington Fruit and Produce Company's new 220,000 sq foot facility.
 - It was assumed that half the plant is used for processing and half for storage, and that an apple packing plant would be similar.
 - Therefore: 220,000 sq ft / 2 = 110,000 sq feet used for storage, with 28 ft ceilings resulting in 3,080,000 total cubic feet for storage.
 - It was assumed that the storage area is not packed floor to ceiling; therefore, areas such as aisles and doorways were subtracted from the total cubic feet resulting in 1,540,000 cubic feet of product that might be treated.
- In warehouses, there are approximately 40.02 pounds of apples per cubic foot (<http://www.aqua-calc.com/page/density-table/substance/Apples>).

Based on these assumptions, the pounds of apples per warehouse would be 1,540,000 cubic feet of warehouse space multiplied by 40.02 lbs. of apples per cubic foot = **61,600,000 pounds of apples.**

Body Weight (BW): The average body weight of an adult (80 kg) was used for all risk assessments.

Equations/Calculations: The following equations were used to calculate handler exposure and risk:

$$\text{Exposure (mg/kg/day)} = \text{Rate (lb ai/lb fruit)} \times \text{UE (mg /lb ai)} \times \text{Amount Treated (lbs/day)} / \text{BW (kg)}$$

Where:

Rate	=	Maximum application rate on product label (lb ai/lb fruit);
UE	=	Unit Exposure (µg ai/lb ai);
Amount Treated	=	Maximum amount treated per day (lb fruit/day); and
BW	=	Body weight (80 kg).

$$\text{Total MOE (for Inhalation Risk)} = \text{NOAEL (mg/kg/day)} / \text{Exposure (mg/kg/day)}$$

6.1.1 Handler Risk Calculation

The mixer/loader inhalation exposure scenarios resulting from thermal fogging of pome fruit are presented below in Table 7. The inhalation MOEs for short- and intermediate-term exposure (11,200 and 3,700, respectively) are not of concern.

Table 7					
Short- and Intermediate term-Inhalation Unit Exposures (mg/lb ai)	Application rate (lb ai/lb fruit) ^a	Amount Treated Daily (lb fruit/day) ^b	Doses (mg/kg/day) ^c	MOEs ^d	
			Short- and intermediate-term	Short-term	Intermediate-term
Mixer/Loading Liquids					
<u>Inhalation</u> Baseline ^e : 0.000219	0.0000053	61,600,000	<u>Inhalation</u> Baseline: 0.00089	<u>Inhalation</u> Baseline: 11.200	<u>Inhalation</u> Baseline: 3.700

- a Application rate is the maximum recommended rates provided on the ecoFOG-80 FDL product label.
- b Amount treated per day value is based on an August 2, 2012 e-mail from Bill Chism, BEAD/EPA.
- c Dose (mg/kg/day) = Unit exposure (mg/lb ai) x App Rate (lb ai/lb fruit) x Amount Treated (lb fruit/day) x %Absorption (100% inhalation assumed) / Body weight (80 kg).
- d MOE = NOAEL/Dose; where the short- and intermediate-term inhalation (NOAEL = 10 mg/kg/day and 3.3 mg/kg/day)
- e Baseline Inhalation: no respirator.

6.2 Post-application Exposure/ Risk

It is anticipated that there may be post-application exposure to treated stored fruit after application; however, there is no dermal POD, therefore, a quantitative occupational dermal post-application assessment was not conducted. In addition, post-application inhalation exposure is expected to be negligible since the proposed eFOG-80 FDL label requires that no entry into the treated room be allowed for 8 hours if there is no ventilation followed by one hour of mechanical ventilation or 24 hours with no ventilation. In case it is necessary to enter the treatment area during the treatment or before ventilation requirements have been met, handlers must wear chemical resistant headgear and a self-contained breathing apparatus (SCBA, MSHA/NIOSH approval number prefix, TC-13F) in addition to the PPE listed in the previous section.